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# ***INTERNET DRUG SALES: IS IT TIME TO WELCOME “BIG BROTHER” INTO YOUR MEDICINE CABINET?***

*Ludmila Bussiki Silva Clifton\**

Prescription drug sales over the Internet continue to grow as the Internet becomes an essential means to communicate and conduct business. The mammoth 150 billion dollar prescription drug industry increasingly lures entrepreneurs to go online and seize a share of industry profits.<sup>1</sup> A 2000 survey indicates that of the ninety-seven million people using the Internet, seventy-four percent access health care information on a regular basis.<sup>2</sup> Among these Internet users are an increasing number of people making purchases from Canadian online pharmacies.<sup>3</sup> As usage of the Internet for e-commerce increases, traditional brick and mortar drugstores follow consumers by opening new storefronts online.<sup>4</sup>

Internet pharmacies have become popular because of the attractive combination of lower prices, convenience, and greater privacy.<sup>5</sup> The aging population of baby boomers, who have greater familiarity with computer usage, will most likely lead to a rise in usage of online

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1. Joanna M. Carlini, *Liability on the Internet: Prescription drugs and the virtual pharmacy*, 22 WHITTIER L. REV. 157, 157 (2000).

2. *Online Health: Number of Users Continues to Grow*, AMERICAN HEALTH LINE (The Nat'l Journal Group Inc.), Aug. 5, 1999.

3. Mary Pat Flaherty & Gilbert Gaul, *Millions of Americans Look Outside U.S. for Drugs*, WASH. POST, Oct. 23, 2003, at A1.

4. Carlini, *supra* note 1, at 157.

5. UNITED STATES GENERAL ACCOUNTING OFFICE, GAO-01-69, *INTERNET PHARMACIES: ADDING DISCLOSURE REQUIREMENTS WOULD AID STATE AND FEDERAL OVERSIGHT* (2000).

pharmacies. Segments of the population, such as the elderly, residents of rural areas, and those homebound because of illness or disability benefit greatly by using the Internet to purchase needed medications.<sup>6</sup> These citizens are in trouble because Internet prescription sales have become a double-edged sword. On the one side, they offer potential cost savings to consumers, and on the other, they rely on an inefficient patchwork of state and federal regulations that are unable to offer uniform and adequate consumer protection. As a result of this lack of uniform regulation, many unscrupulous and sometimes illegitimate online pharmacies threaten the innocent consumer's life and well-being.<sup>7</sup>

Currently, states have the responsibility for establishing and enforcing the procedures necessary for operating an online drugstore such as licensing and regulating out-of-state pharmacies that want to ship medications to residents of the state. As a result, consumer protection is largely dependent upon state regulations. Unfortunately, the states' regulatory mechanism is marked by discrepancies, because some states take a more proactive role, while other states leave the field totally unregulated.<sup>8</sup> States' budgets vary widely. Thus, some poorer states simply do not have the resources to provide meaningful oversight of Internet drug sales. At the federal level, several administrative agencies, such as the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), and the Department of Justice (DOJ), provide limited and often times overlapping regulations of online pharmacies. State and federal governments currently have an inefficient regulatory regime leaving many loopholes.

Because of this current inefficiency, Congress must enact legislation to enable the federal agencies to implement the necessary regulations to safeguard consumers. Part I of this comment provides background information into the reasons for the popularity in buying prescriptions online. Part II provides an overview of the types of online pharmacies

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6. Kristin Yoo, *Self-Prescribing Medication: Regulating Prescription Drug Sales on the Internet*, 20 J. MARSHALL J. COMPUTER & INFO. L. 57, 61 (2001).

7. Carlini, *supra* note 1, at 159.

8. In order to establish a nonresident pharmacy to ship, mail, or deliver drugs in Mississippi, all that is needed is to register with the state. The State Board of Pharmacy relies on the disclosure by the applicant and does not require the substantiation of any records. See Application for Non-Resident Pharmacy Permit 2004-2005, Mississippi State Board of Pharmacy [hereinafter Mississippi State Board of Pharmacy], available at <http://www.mbp.state.ms.us/nrretailapp.pdf> (last visited May 13, 2004).

and how they operate in the current legislative vacuum. Part III discusses the various states' attempts at regulating online pharmacies.<sup>9</sup> Part IV outlines the existing federal regulatory patchwork among the various agencies. Finally, Part V argues that the only feasible solution is to have the federal government create a uniform body of law dealing specifically with online drug sales, thereby targeting the problems that are unique to online drug prescribing and online drug dispensing.

## I. REASONS FOR THE POPULARITY OF INTERNET PHARMACIES

### A. Demand: Americans Go Online for Convenience, Privacy, and Price

Historically, the United States has had one of the safest systems in the world to deliver prescription drugs to the consumer, because the Food and Drug Administration (FDA) has been able to effectively regulate the domestic sale of prescription drugs.<sup>10</sup> Prior to the advent of Internet pharmacies, the sale of prescription drugs were done pursuant to a rigid screening process. Drugs could only be purchased from brick and mortar pharmacies or by well-known mail order outlets. This limitation did not represent a pocketbook issue to consumers because prescription drug prices did not impose as much of a financial burden on consumers as they do today. Likewise, importation of drugs from overseas was not as readily available as today. Since the advent of online pharmacies, there has been an increase in illegal sales of prescription drugs, unsafe foreign pharmacies, and fraudulent online pharmacies.<sup>11</sup>

Some online pharmacies are a mere extension of the "mail order pharmacy," which only fills current prescriptions written by a doctor who has seen the patient.<sup>12</sup> This model is not the danger. The current risks to the health care of citizens reside in the other types of online pharmacies.

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9. Part III offers an overview and is by no means an exhaustive or even complete list of all state regulations in the field.

10. Food and Drug Administration, *The Risks of Buying Medicines From Across the Border or Around the World*, at <http://www.fda.gov/cder/consumerinfo/borderArticle.pdf> (last visited Apr. 10, 2004).

11. Mary Pat Flaherty & Gilbert Gaul, *U.S. Prescription Drug System Under Attack*, WASH. POST, Oct. 19, 2003, at A1.

12. Yoo, *supra* note 6, at 63.

A riskier type of online pharmacy is designed like a patient-doctor office visit without any face-to-face consultation.<sup>13</sup> Generally, patients fill out a brief medical questionnaire which is then transmitted to the drug retailer via the Internet.<sup>14</sup> At the receiving end is an "online physician" who reviews the information and ships the drugs directly to the "patient's" home.<sup>15</sup> Through this arrangement the consumer realizes greater privacy and convenience.<sup>16</sup> However, the lack of patient-physician interaction is dangerous in that it does not allow the physician to examine the patient, nor does it allow the physician to ask probing questions to determine whether the particular medication requested is indeed suited for a particular patient. The physician is also unable to advise the patient of potential side effects or under what circumstances the patient should seek help from his primary care doctor.

Although privacy and convenience may factor in to a consumer's decision to buy prescriptions online, price may be the main motivation.<sup>17</sup> The emergence of Internet drugstores affects market conditions of the traditional pharmacy sector by introducing an additional venue for prescription sales. Internet pharmacies gain a competitive advantage through lower operating costs than those of traditional brick and mortar locations. These savings are passed on to consumers through lower prices,<sup>18</sup> as evidenced in a 2001 study by the General Accounting Office which found that prescription prices for certain medications were cheaper online than at traditional drugstores.<sup>19</sup>

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13. Amy J. Oliver, *Internet Pharmacies: Regulation of a Growing Industry*, 28 J.L. MED. & ETHICS 98, 98 (2000).

14. *Id.*

15. *Id.*

16. Carlini, *supra* note 1, at 158.

17. UNITED STATES GENERAL ACCOUNTING OFFICE, GAO/T-HRD-93-5, PRESCRIPTION DRUGS: COMPANIES TYPICALLY CHARGE MORE IN THE UNITED STATES THAN IN CANADA (1993).

18. Internet Tax Non-Discrimination Act of 2003, S. 150, 108th Cong. § 2 (2003).

19. UNITED STATES GENERAL ACCOUNTING OFFICE, GAO-02-280R, PRESCRIPTION DRUGS: PRICES AVAILABLE THROUGH DISCOUNT CARDS AND FROM OTHER SOURCES (2001).

### B. Legislative Initiatives

Various members of Congress have introduced legislation in an effort to keep Internet prescription prices from rising. Internet sales are temporarily exempted from taxation.<sup>20</sup> For example, the North American Prescription Price Act of 2003, if approved, would make the temporary tax exemption into a permanent tax moratorium on Internet purchases.<sup>21</sup> If this legislation is passed, the lack of taxation on prescriptions purchased online will present a source of savings for consumers. In order to remain competitive, traditional pharmacies will likely have to cut their prices. Ultimately, this Act will allow consumers to purchase prescription drugs at lower prices either online or at traditional pharmacies.<sup>22</sup>

Another legislative effort is Representative John J. Duncan's (R-TN) proposal to give drug manufacturers an income tax credit.<sup>23</sup> This tax credit will be accessible if the drug manufacturers can certify that the prices charged in the United States are not greater than the prices charged for the same drugs in Canada or Mexico.<sup>24</sup> The credit will cause Internet pharmacies to lose some of their price advantage and thus likely curb some growth in online pharmaceutical sales.

An additional measure introduced in the Senate is the Preserving Prescription Drug Act.<sup>25</sup> This legislation would disallow tax credits and deductions for companies that discriminate against Canadian pharmacies that pass their discounts along to U.S. consumers.<sup>26</sup> The effect would be to force drug manufacturers to lower their prices in the United States to match the lower prices offered to Canadian consumers.<sup>27</sup>

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20. 47 U.S.C. § 151 (2003).

21. S. 150.

22. *Id.*

23. North American Prescription Price Equity of 2003, H.R. 354, 108th Cong. § 2 (2003).

24. *Id.*

25. See Preserving Prescription Drug Discounts Act, S. 477, 108th Cong. § 2801 (2003).

26. *Id.*

27. *Id.*

## II. AN OVERVIEW OF ONLINE PHARMACIES

### A. Types of Online Pharmacies

Online pharmacies are divided into three broad categories: traditional online pharmacy, prescribing-based site pharmacy, and rogue pharmacy.<sup>28</sup> The first category, traditional online pharmacy, operates much the same way as mail order pharmacies.<sup>29</sup> The pharmacy uses state-licensed pharmacists and requires consumers to have a valid prescription sent to them before an order may be filled online.<sup>30</sup> As a safety measure, the pharmacy may on a case-by-case basis check with the prescribing physician before mailing the requested order.<sup>31</sup>

The second category, prescribing-based site, performs a two-step service.<sup>32</sup> The first step is diagnosis. The patient fills out a general medical questionnaire, including medications the patient may be currently taking and the patient's medical history. Using this information, the online doctor offers to diagnose the patient. Once the doctor gives a diagnosis, the online doctor is then able to prescribe the medication.

The third category, rogue pharmacy, presents the greatest danger to consumers.<sup>33</sup> This type of online pharmacy allows a customer to purchase medication without any prescription and without any online diagnostic service.<sup>34</sup> Consumers who try to self-diagnose may be unaware of the possible side effects of certain medications. Those consumers also risk an adverse reaction with other prescriptions they may already be taking.<sup>35</sup>

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28. Carlini, *supra* note 1, at 159.

29. Yoo, *supra* note 6, at 63.

30. Flaherty & Gaul, *supra* note 11.

31. Yoo, *supra* note 6, at 63.

32. *Id.*

33. *Id.* at 64.

34. *Id.* at 65.

35. *Id.*

### B. Dispensing and Prescribing

A distinction needs to be made between dispensing and prescribing medications over the Internet.<sup>36</sup> Internet dispensing involves the delivery of prescription drugs by an online pharmacy.<sup>37</sup> Internet prescribing arises when the online pharmacy prescribes the drug to the consumer absent a physical examination.<sup>38</sup> While both methods pose significant health risks, the latter is more dangerous because the pharmacy plays the role of both doctor and pharmacist. This dual role can be potentially fatal to the consumer.<sup>39</sup> Prior to the advent of the Internet, prescription drugs were not available without a face-to-face encounter between physician and patient.<sup>40</sup> A patient's knowledge of a particular prescription drug was usually limited to the information provided by his or her doctor. With the advent of the Internet, this is no longer the case.

There is widespread agreement over the ability of patients to get information and drugs online; however, there is disagreement between the Federation of State Medical Boards (FSMB) and the American Medical Association (AMA) on the desirability of online prescribing absent a physician-patient relationship. In April 2000, the FSMB delineated its policy on online prescribing:

Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings. Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.<sup>41</sup>

While the FSMB allows some degree of online prescribing, the AMA takes a stricter view on the matter by requiring a prior physician-patient relationship in order to provide medical care. The Association highlights the need for physicians to recognize the

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36. Kara M. Friedman, *Internet Prescribing Limitations and Alternatives*, 10 ANNALS HEALTH L. 139, 143 (2001).

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.* at 140.

41. FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, MODEL GUIDELINES FOR THE APPROPRIATE USE OF THE INTERNET IN MEDICAL PRACTICE (2002) [hereinafter FSMB], available at <http://www.fsmb.org> (last visited May 13, 2004).



importance of establishing and maintaining a physician-patient relationship and to be aware of patients' rights and privacy whether or not there has been physical contact between the physician and the patient.<sup>42</sup>

*C. The Rise of Online Prescribing: Lowered Managed Care Expectations and the FDA's Advertising Regulation*

In recent years, managed care has lowered expectations of the doctor-patient relationship because it has caused patients to switch doctors whenever a doctor is dropped from the managed care organization's approved provider list.<sup>43</sup> Patients have lost the closeness with their physicians that they once had, while the physician's role is no longer that of a counselor, friend, or support system.<sup>44</sup> Today, consultations with a physician are too brief for the doctor to get to know the patient.<sup>45</sup> As a result, the managed care environment has degraded the doctor-patient relationship and has led to lower expectations.

In addition to lowered expectations of the doctor-patient relationship, pharmaceutical companies have increased direct-to-consumer advertising, thereby in the patient's eyes reducing the need for a physician to be involved in determining what drug therapy to use.<sup>46</sup> While the FDA discourages direct advertising of prescription drugs to consumers, direct advertising is permitted.<sup>47</sup> The first FDA regulations for prescription drug advertising were established in 1963.<sup>48</sup> They require drug manufacturers to disclose all adverse information about the prescription drug, including its side effects and contraindications.<sup>49</sup> It was not until 1985 that the FDA lifted the moratorium on "Direct-to-Consumer" advertising, but it continued to discourage

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42. *Id.*

43. Ronald L. Scott, *Cybermedicine and Virtual Pharmacies*, 103 W. VA. L. REV. 407, 411 (2001).

44. *Id.*

45. *Id.*

46. Andrew Somora, *Direct-to-Consumer Advertising: Are Consumers Being Informed?*, 8 KAN. J. L. & PUB. POL'Y 205, 206 (1999).

47. *Id.*

48. 15 U.S.C. § 55 (a)(1) (1964).

49. *Id.*

the practice.<sup>50</sup> In 1999, the FDA relaxed its rules concerning broadcast advertising and issued final regulations for the industry.<sup>51</sup> These regulations required the industry to disclose fully the risks of each prescription drug.<sup>52</sup>

As a result of increased advertising by drug manufacturers via the web, television, radio, and email subscription lists, patients have gained new knowledge of the many drugs available to treat their problems, allowing for self-diagnosis.<sup>53</sup> This is a marked shift in philosophy from “doctor knows best”<sup>54</sup> to patients now asking their doctors for particular drugs.<sup>55</sup> Putting patients in the “driver’s seat” does have the benefit of allowing greater control over one’s own health decisions, which can be crucial at a time when many citizens are uninsured, underinsured, or lacking prescription drug coverage.<sup>56</sup> However, allowing direct-to-consumer advertising by drug manufacturers causes some consumers to undermine the physician’s role by self-medicating. Online pharmacies make this possible by eliminating the need for a doctor to physically examine a patient prior to prescribing medication.<sup>57</sup>

The FDA’s progressive relaxation of prescription advertising to consumers has created problems for state regulation of online pharmacies. This has allowed patients to learn about dangerous prescription drugs while the Internet has become a viable way to purchase them. States have the primary responsibility for licensing pharmacies, but faced with the public’s ability to acquire dangerous drugs, the states are unsure how to proceed. State legislatures have

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50. Somora, *supra* note 46, at 205.

51. April L. Foreman, *Web of Manipulation: The Learned Intermediary Doctrine and Direct-to-Consumer Advertising on the World Wide Web*, 35 J. MARSHALL L. REV. 97, 100-101 (2001).

52. *Id.*

53. *Id.* at 102; *see also* Prozac dosage information, at [http://www.mentalhealth.com/drug/p30-p05.html#Head\\_1](http://www.mentalhealth.com/drug/p30-p05.html#Head_1) (last visited Apr. 7, 2004); Advertisement for Nexium, “the purple pill,” along with dosage information, at <http://www.purplepill.com> (last visited Apr. 7, 2004).

54. *See, e.g.,* Perez v. Wyeth Labs. Inc, 734 A.2d 1245, 1255 (N.J. 1999).

55. *Id.*

56. Vida Foubister, *Getting Prescriptions to the People*, available at <http://www.ama-assn.org/sci-pubs/amnews/pick-00/prsa1023.htm> (last visited Nov. 22, 2003) (noting thirty-one percent of seniors lack prescription drug coverage).

57. For an example of online pharmacy that does not require physical examination prior to prescribing medication, *see* Cheap-Online-Pharmacy.org, at <http://www.cheap-online-pharmacy.org> (last visited May 13, 2004).

reacted by framing the question as, How do we stop this? rather than, How do we regulate this?<sup>58</sup> The reality is that the Internet will not simply disappear. As long as this mode of communication is available, there will be pharmacists and doctors willing to take the risk and prescribe medication online. Likewise, there will be individuals desperate for more affordable drugs who are willing to jeopardize their own health in an attempt to secure needed medication. Those who are terminally ill may be the most susceptible to purchasing unapproved drugs because of their desire to prolong life regardless of the risks.<sup>59</sup>

### III. STATE REGULATORY FRAMEWORK

#### *A. The implications of the doctor-patient relationship for online medicine*

States have historically regulated health care providers and health insurance.<sup>60</sup> Prescription dispensing is another related area that states have historically regulated.<sup>61</sup> Consequently, states are regulators of both the professionals who render medical advice as well as the businesses that sell the medicine. Accordingly, the states play a key role in protecting consumers from the risks involved in buying prescription drugs online.

Unfortunately, there are widespread discrepancies between state laws regarding online drug dispensing and prescribing.<sup>62</sup> Some states have no regime to regulate online drug sales.<sup>63</sup> Other states require patients to have a valid physician-patient relationship and a physical examination before allowing a doctor to prescribe drugs.<sup>64</sup> This lack of uniformity allows a resident from one state to be diagnosed by an online physician in a less regulated state. The question over what constitutes a valid doctor-patient relationship becomes crucial in order to safeguard consumers.

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58. Scott, *supra* note 43, at 422.

59. Friedman, *supra* note 36, at 146.

60. FSMB, *supra* note 41.

61. See, e.g., MD. REGS. CODE tit. 10, § 7, chp. 02, reg. 15 (2003).

62. Sean P. Haney, *Pharmaceutical Dispensing in the "Wild West": Advancing health care and protecting consumers through the regulation of online pharmacies*, 42 WM. AND MARY L. REV. 575, 603-606 (2000).

63. Mississippi State Board of Pharmacy, *supra*, note 8.

64. *Id.*

An important issue that arises is at what point the doctor-patient relationship begins.<sup>65</sup> The determination of what constitutes a doctor-patient relationship may be restricted to those instances in which both parties are physically present. Alternatively, it can be broadened to incorporate telemedicine, which allows for a physician in another state to practice medicine across state borders without ever having to be physically present in that state.<sup>66</sup> In such cases there is never a face-to-face meeting with the physician.<sup>67</sup> The FSMB takes the position that the doctor-patient relationship begins when an individual seeks assistance from a physician on a health-related matter.<sup>68</sup> The FSMB further elaborates, "[T]he relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient and the patient agrees to that treatment, whether or not there has been a personal encounter between the physician (or other supervised health care practitioner) and patient."<sup>69</sup>

Of the states with a prescription regulation regime, Maine, New Hampshire, and Vermont require that "any medical service to a patient requires a professional licenser in the state in which the patient encounter will occur."<sup>70</sup> A physician needs to be licensed and therefore in compliance with the laws of the state in which the patient lives. This allows these states to restrict physicians licensed in other states from rendering medical advice to its residents. In these states a patient-doctor relationship does not occur unless a doctor is licensed in that state.

Oklahoma, Maryland, Alabama, Ohio, and Texas have also adopted guidelines for online drug sales.<sup>71</sup> California, Illinois, and Oregon have been even more proactive by taking steps to hold physicians who prescribe medication in violation of Internet communication standards accountable for their actions.<sup>72</sup> Arizona, California, and Virginia have enacted measures to create standards for prescribing medications online.<sup>73</sup> Delaware, Michigan, and New York have introduced similar

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65. *Id.*

66. FSMB, *supra* note 41.

67. Scott, *supra* note 43, at 412-413.

68. FSMB, *supra*, note 41.

69. *Id.*

70. Friedman, *supra* note 36, at 160.

71. *Id.*

72. *Id.* at 161.

73. *Id.*

legislation.<sup>74</sup> However, California remains the only state with a full-time agent dedicated to investigating online pharmacies.<sup>75</sup>

Following in the footsteps of California, over a dozen other states have taken some kind of action against Internet pharmacies. For example, Kansas has prohibited several pharmacies from operating illegal websites.<sup>76</sup> These sites made false promises of a cure by advising consumers to “cancel surgery, radiation or chemotherapy in favor of herbal cures that cost hundreds of dollars.”<sup>77</sup> In another instance a website recommended St. John’s Wort as an alternative treatment for HIV/AIDS.<sup>78</sup> It is well known in the medical community that St. John’s Wort interferes with HIV medications.<sup>79</sup>

The National Association Boards of Pharmacy (NABP)<sup>80</sup> is a national organization that represents all of the states’ boards of pharmacy. Since 1904, the NABP has worked alongside states in developing, implementing, and enforcing uniform standards.<sup>81</sup> The NABP is responsible for the development of the North American Pharmacist Licensure Examination and other tests that are utilized by the state boards in order to assess the competence of candidates to practice pharmacology.<sup>82</sup>

In the spring of 1999, NABP created the Verified Internet Pharmacy Practice Sites (VIPPS)<sup>83</sup> to address concerns about the potential dangers associated with online pharmacies. The goal of the program is to encourage Internet pharmacies to comply with the licensing and inspection laws of the states in which they are located as well as each

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74. *Id.*

75. Flaherty & Gaul, *supra* note 11.

76. John Henkel, *Buying Drugs Online: It's Convenient and Private, but Beware of 'Rogue Sites'*, FDA CONSUMER, Jan.-Feb. 2000 (revised in Jun. 2000 & Mar. 2001), at [http://www.fda.gov/fdac/features/2000/100\\_online.html](http://www.fda.gov/fdac/features/2000/100_online.html) (last visited May 13, 2004).

77. Press Release, Federal Trade Commission, “Operation Cure.All” Wages New Battle in Ongoing War Against Internet Health Fraud (Jun. 14, 2001), available at <http://www.ftc.gov/opa/2001/06/cureall.htm> (last visited May 13, 2004).

78. *Id.*

79. *Id.*

80. See generally National Association Board of Pharmacy website, at <http://www.nabp.net> (last visited Sept. 9, 2003). The NABP is made up of the Boards of Pharmacy from the fifty states, the District of Columbia, three U.S. territories, nine Canadian Provinces and four Australian states.

81. *Id.*

82. *Id.* at <http://www.nabp.net/vipps/intro.asp> (last visited Nov. 22, 2003).

83. *Id.*

state to which they ship pharmaceutical goods.<sup>84</sup> In addition, VIPPS requires that the pharmacies must provide meaningful consultation between the patient and the pharmacist.<sup>85</sup> In return for complying with the requirements, pharmacies can then display the VIPPS logo on their website.<sup>86</sup> This is important because it creates an aura of credibility for the online pharmacy; however, VIPPS has no express requirement that pharmacies only fill prescriptions for patients who have a valid physician prescription.<sup>87</sup>

*B. A Major Problem for State Regulation of Online Pharmacies:  
Seniors and Foreign Pharmacies*

A central reason why states cannot effectively regulate online pharmacies is that much of the commerce is between citizens of the state and foreign pharmacies. The U.S. Department of Customs estimates that approximately ten million U.S. citizens per year enter the United States with foreign medications. An additional two million prescription packages arrive by mail from countries in Asia; still more purchases are made from Canadian online pharmacies. The Commerce Clause of the Constitution gives Congress the power to "regulate commerce with foreign Nations."<sup>88</sup> Hence, states do not have the power to set up rules prohibiting entry of foreign drugs into the country.

The sale of prescription drugs from foreign pharmacies is particularly troublesome. Though drugs sold over the Internet may be legal in the country where the pharmacy is located, they may not have been approved by the FDA for use in the United States.<sup>89</sup> These drugs have not undergone the rigorous trials the FDA imposes before authorizing a new drug to be marketed in the United States.<sup>90</sup> According to the AMA, there are between three-hundred and four-hundred Internet sites selling prescription drugs, approximately half of

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84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. U.S. Const., art. I, § 8.

89. Markian Hawryluk, *Drugs without borders: When prescription drugs go over the line*, AM. MED. NEWS (Oct. 22/29, 2001), at <http://www.amaassn.org/amednews/2001/10/22/gvsa1022.htm>.

90. *Id.*

which are based outside the United States.<sup>91</sup> The FDA recently estimated that two million parcels of prescription drugs enter the United States for personal use each year.<sup>92</sup> Since the sites are not required to post their physical addresses, it is difficult for consumers to be confident in the pharmacy's location and reputation.<sup>93</sup> Lack of a known physical location also makes it difficult for the states to investigate these pharmacies because of questions regarding jurisdiction. Even though it is illegal for a foreign pharmacy to ship drugs into the United States,<sup>94</sup> enforcement is difficult because those overseas pharmacies do not come within the jurisdiction of the United States.<sup>95</sup> For instance, in Mexico there is no federal regulatory body, such as the FDA, overseeing drug safety.<sup>96</sup> This has led the FDA to warn consumers of the potential risks involved in purchasing a medication from an unregulated site.<sup>97</sup> One such risk is that the prescription may be coming from overseas. The FDA has found that few imported drugs have adequate instruction labels in English.<sup>98</sup>

Despite the potential harmful effects of purchasing prescriptions online, many consumers are still attracted to this channel. The main

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91. *Id.*

92. Preserving Access to Safe, Affordable Canadian Medicines Act of 2003, H.R. 847, 108th Cong. § 2 (2003).

93. UNITED STATES FOOD AND DRUG ADMINISTRATION, BUYING MEDICINE AND MEDICAL PRODUCTS ONLINE [hereinafter BUYING MEDICINE ONLINE], at <http://www.fda.gov/oc/buyonline/default.htm> (last visited May 13, 2004).

94. H.R. 847.

95. Yoo, *supra* note 6, at 57.

96. *Id.*

97. BUYING MEDICINE ONLINE, *supra* note 91. On its website, FDA issues the following warning to consumers who shop for medicines on line:

You may receive a contaminated or counterfeit product, the wrong product, an incorrect dose, or no product at all. Taking an unsafe or inappropriate medication puts you at risk for dangerous drug interactions and other serious health consequences. Getting a prescription drug by filling out a questionnaire without seeing a doctor poses serious health risks. A questionnaire does not provide sufficient information for a health-care professional to determine if that drug is for you or safe to use, if another treatment is more appropriate, or if you have an underlying medical condition where using that drug may be harmful.

*Id.*

98. See Hawryluk, *supra* note 89.

motivation is potential cost savings.<sup>99</sup> According to the General Accounting Office (GAO), a consumer in the United States pays on average one-third more for the same prescription drug as would a consumer in Mexico or Canada.<sup>100</sup> In addition, costs for prescription drugs have risen on average over twelve percent a year between 1993 and 1998, while overall health care expenditures only rose five percent per year within the same time period.<sup>101</sup>

Senior citizens are the most vulnerable online prescription consumer population, due in part to the fact that one-third of the senior population is without prescription drug insurance.<sup>102</sup> These seniors pay on average fifteen percent more for a prescription than those who have drug coverage.<sup>103</sup> Seniors who do have coverage typically use twenty-one prescriptions a year, compared with sixteen for those who do not have insurance coverage.<sup>104</sup> The average senior citizen has two to twenty-one chronic conditions.<sup>105</sup> A drug for one chronic condition can cost anywhere from \$500 to \$3,000 per year.<sup>106</sup> In light of this predicament, many people go to Canada or Mexico to buy prescription drugs or choose to purchase them online.<sup>107</sup> Recently, cities and states faced with budget considerations have also started filling their prescription orders from Canadian suppliers in order to afford the costs of providing government employees with a prescription coverage benefit.<sup>108</sup>

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99. UNITED STATES GENERAL ACCOUNTING OFFICE, *supra* note 17; UNITED STATES GENERAL ACCOUNTING OFFICE, GAO/HRD 92-128, *PRESCRIPTION DRUGS: CHANGES IN PRICES FOR SELECTED DRUGS* (1992).

100. Medicare Payment Restoration and Benefits Improvement Act of 2003, H.R. Res. 26, 108th Cong. (2003).

101. *Id.*

102. Foubister, *supra* note 56.

103. H.R. Res. 26.

104. *See* Foubister, *supra* note 56.

105. *Id.*

106. *Id.*

107. Julie Appleby, *Firm fights for Canadian Drugs*, USA TODAY, Oct. 7, 2003, at 3B.

108. *See* Prescription Drug Price Parity for American Act, S. 2244, 107th Cong. §2 (2002); *see also* H.R. 4954, 107th Cong. (2002).



#### IV. FEDERAL REGULATORY FRAMEWORK

##### *A. The Current Framework of Federal Regulatory Oversight of Internet Pharmacies*

The federal regulatory framework in the United States for Internet pharmacies consists of a patchwork of regulations promulgated from various federal agencies. These agencies include the Food and Drug Administration (FDA), Federal Trade Commission (FTC), Department of Justice (DOJ), Federal Bureau of Investigation (FBI), U.S. Customs, Drug Enforcement Agency (DEA), and the National White Collar Crime Center.

##### *1. The Food and Drug Administration*

The FDA operates under the Department of Health and Human Services (HHS). The Secretary of HHS delegates authority to the FDA Commissioner.<sup>109</sup> The FDA regulates the field of prescription drugs via the Federal Food, Drug and Cosmetic Act (FDCA).<sup>110</sup> The Act sets forth a detailed body of regulation for drugs. It prohibits the “introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded.”<sup>111</sup> An article is considered misbranded if it is dispensed without a valid physician’s order completed in accordance with the law.<sup>112</sup> In addition, the FDCA prohibits the interstate shipment, including importation, of unapproved new drugs.<sup>113</sup> The FDA also

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109. 21 C.F.R. § 5.10 (2003).

110. Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (2000).

111. 21 U.S.C. § 331(a) (2000).

112. See Friedman, *supra* note 36, at 147; 21 U.S.C. 353(b) (2000).

113. See UNITED STATES FOOD AND DRUG ADMINISTRATION, IMPORTATION OF PRESCRIPTION MEDICINE/DRUGS, at [http://www.fda.gov/ora/import/traveler\\_alert.htm](http://www.fda.gov/ora/import/traveler_alert.htm) (last visited May 13, 2004).

Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs, that have not received FDA approval to demonstrate they meet the federal requirements for safety and effectiveness. It is the importer’s obligation to demonstrate to FDA that any drugs offered for importation have been approved by FDA.

*Id.* (citing 21 U.S.C. §§ 331(d)-355(a)) (2000).

enforces the provisions of the Fair Packaging and Labeling Act<sup>114</sup> which requires packages to have accurate information. Currently, the FDA is unable to enforce the laws HHS has delegated to it because it simply does not have the manpower to inspect every package at the border or in the mail.<sup>115</sup> Recognizing its limited resources, in 2001 the FDA sent a memo to HHS Secretary Tommy Thompson proposing that "all medication mailed into the United States be returned to its sender, except for a fraction that doctors could import for gravely ill patients."<sup>116</sup> The Secretary has yet to respond.<sup>117</sup>

## 2. The Federal Trade Commission

The FTC's power to regulate online pharmacies is derived from its power to regulate interstate commerce via the Federal Trade Commission Act.<sup>118</sup> The Act prohibits "unfair or deceptive practices in or affecting commerce."<sup>119</sup> Specifically the FTC is "responsible for the administration of a variety of statutes, which in general, are designed to promote competition and to protect the public from unfair and deceptive acts and practices in advertising and marketing of goods and services."<sup>120</sup> Relying on its power to regulate deceptive advertising practices, the FTC in July 1999 announced a program called "Operation Cure All" which targets false claims of products and treatments advertised as cures for certain diseases.<sup>121</sup>

In its first two years of enforcement, the FTC identified eight-hundred sites and newsgroups containing questionable practices.<sup>122</sup> As a result of the FTC's enforcement actions, four companies entered into a consent decree with the government over the FTC charges of deceptive health claims.<sup>123</sup> These charges included sites that claimed to "cure arthritis with a fatty acid derived from beef tallow, to treat

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114. 15 U.S.C. § 1451 (2000).

115. Flaherty, *supra*, note 3.

116. *Id.*

117. *Id.*

118. 15 U.S.C. § 45 (2000).

119. *Id.*

120. 16 C.F.R. § 0.1 (2004).

121. See generally Federal Trade Commission, at <http://www.ftc.gov> (last visited on Nov. 22, 2003).

122. Henkel, *supra* note 76.

123. *Id.*

cancer and AIDS with a Peruvian plant derivative and to treat cancer and high blood pressure with magnetic devices.”<sup>124</sup> The FDA is participating with the FTC in “Operation Cure All” by issuing “cyber letters” to advise operators of Internet pharmacy websites that the products being marketed may not be in compliance with federal law.<sup>125</sup>

### 3. *The Department of Justice*

The DOJ oversees subordinate agencies, including the DEA and the FBI.<sup>126</sup> The Computer Crime and Intellectual Property Section (CCIPS) functions within the DOJ and its purpose is to patrol the Internet in an effort to uncover illegal activity.<sup>127</sup> In addition, it has created a division to provide consumers with information regarding Internet fraud. Consumers may file a formal complaint against an Internet pharmacy, which will initiate an investigation by the DOJ.<sup>128</sup>

### 4. *The Drug Enforcement Agency*

Congress’ ability to regulate controlled substances flows from its power to regulate interstate commerce<sup>129</sup> due to its finding that “controlled substances distributed locally usually have been transported in interstate commerce immediately before distribution.”<sup>130</sup> The DEA is responsible for enforcing the Controlled Substances Act and the Comprehensive Drug Abuse Prevention and Control Act of 1970.<sup>131</sup> Title II of the Comprehensive Drug Abuse Prevention and Control Act regulates the manufacture and distribution of narcotics

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124. *Id.*

125. *Id.*

126. 28 C.F.R. § 01 (2004).

127. Friedman, *supra* note 33, at 152.

128. UNITED STATES DEPARTMENT OF JUSTICE, HOW TO REPORT A COMPLAINT ABOUT WASTE, FRAUD, ABUSE, OR MISCONDUCT IN THE DEPARTMENT OF JUSTICE, at <http://www.usdoj.gov/fraud.htm> (last visited May 13, 2003).

129. U.S. Const., art. I, § 8.

130. 21 U.S.C. § 801 (2004).

131. *Id.*

and chemicals used in the production of controlled substances.<sup>132</sup> The DEA has issued guidance entitled "Dispensing and Purchasing Controlled Substances Over the Internet" aimed at educating prescribers and pharmacists about the use of the Internet in the sale of controlled substances.<sup>133</sup> More recently, the DEA has targeted specific prescriptions which have seen an increase in abuse, particularly medication to treat severe pain, such as OxyContin.<sup>134</sup> A recent Internet search for OxyContin, however, yielded a website selling the drug and luring consumers with its promise of "no prescription" necessary.<sup>135</sup>

### 5. The Federal Bureau of Investigation

The FBI also plays a role in the federal enforcement against unscrupulous online pharmacies.<sup>136</sup> The agency has dedicated a special portion of its website to alert senior citizens to the danger of purchasing prescription drugs online.<sup>137</sup> The FBI has partnered with the National White Collar Crime Center (NW3C) to provide for an Internet Fraud Complaint Center (IFCC).<sup>138</sup> The IFCC's mission is to address fraud committed specifically over the Internet. For victims of Internet fraud, the IFCC provides a convenient and easy-to-use reporting mechanism that alerts authorities to a suspected criminal or civil violation.<sup>139</sup> The IFCC's expertise in dealing exclusively with Internet fraud allows law enforcement and regulatory agencies at all

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132. Controlled Substances Act, 21 U.S.C. § 801 (2000); *see also* UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, CONTROLLED SUBSTANCES ACT, at <http://www.usdoj.gov/dea/agency/csa.htm> (last visited May 13, 2004).

133. Friedman, *supra* note 33, at 150.

134. *See generally* UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, OXYCONTIN, at [http://www.dea.gov/concern/oxycodone\\_factsheet.html](http://www.dea.gov/concern/oxycodone_factsheet.html) (last visited May 13, 2004).

135. *See, e.g.*, <http://www.oxycontin-oxycodone.com/brandname-oxycontin.htm> (last visited May 13, 2004).

136. *See generally* FEDERAL BUREAU OF INVESTIGATION, FRAUD TARGET: SENIOR CITIZENS, at <http://www.fbi.gov/majcases/fraud/seniorsfam.htm> (last visited May 13, 2004).

137. *Id.*

138. FEDERAL BUREAU OF INVESTIGATION, FRAUD ON THE INTERNET, at <http://www.fbi.gov/majcases/fraud/internetschemes.htm> (last visited May 13, 2004).

139. *See* Internet Fraud Complaint Center website, at <http://www.ifccfbi.gov/index.asp> (last visited May 13, 2004).

levels to quantify fraud patterns and provide statistical data on current fraud trends.<sup>140</sup>

## V. INVITING THE FEDERAL GOVERNMENT: THE NEED FOR UNIFORM REGULATION

### A. *Do we need new legislation, or can agencies act under existing statute?*

#### 1. *The Non-delegation doctrine*

The first issue that arises when making the case for uniform regulation via federal agencies is whether Congress can delegate its legislative powers to an agency. The Constitution states that “all legislative powers . . . shall be vested in a Congress of the United States.”<sup>141</sup> Section 8 of Article 1 provides Congress with the power to “make all laws which are necessary and proper for carrying into execution . . . vested by this Constitution in the Government of the United States.”<sup>142</sup> As Dean William Fox aptly points out,<sup>143</sup> the Constitution appears to give exclusive power to Congress to legislate while permitting Congress to authorize other governmental bodies to legislate in its place.<sup>144</sup>

The Supreme Court recognized early on in *Wayman v. Southard*<sup>145</sup> that Congress could not be expected to run the daily operations of the whole country. The Court accepted that Congress had the power to delegate but limited Congress from giving broad delegations to administrative agencies.<sup>146</sup> The Court required Congress to establish the general framework of the regulatory program while leaving to the agencies the implementation decisions.<sup>147</sup>

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140. *Id.*

141. U.S. Const, art. I, § 1.

142. U.S. Const, art. I, § 8.

143. WILLIAM F. FOX, JR., UNDERSTANDING ADMINISTRATIVE LAW 32 (3rd ed. 1997).

144. *Id.*

145. *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1 (1825).

146. *Id.* at 27.

147. *Id.* at 27.

The Court did not use the non-delegation doctrine to invalidate Congress' actions until 1935. That year the Supreme Court, on two separate occasions, struck down Congress' grant of legislative power to the Executive and invalidated two of Roosevelt's New Deal programs.<sup>148</sup> The Court has not used the non-delegation doctrine to invalidate Congress' delegation of power to agencies and other governmental bodies since 1935.<sup>149</sup>

Federal agencies are created by statute.<sup>150</sup> Each agency's scope of authority is limited by Congress and is delineated in the agency's enabling act.<sup>151</sup> The Administrative Procedure Act (APA)<sup>152</sup> sets forth the procedures that all agencies, unless Congress has provided for an exception, must follow.<sup>153</sup> The enabling acts and the APA set forth the minimum requirements for agencies that are then allowed to fill in the gaps by exercising discretion.<sup>154</sup> This discretion derives from Congress' belief that agencies have the expertise in their particular area of regulation and should be in charge of developing the detailed regulation that is necessary to carry out Congress' will.<sup>155</sup>

## 2. Preemption

The second issue that arises when calling for federal regulation of Internet prescription sales is what happens should there be an inconsistency between a new federal law and a state statute. In *Gibbons v. Ogden*,<sup>156</sup> Justice Marshall stated that if there is a "collision" between a valid constitutional Act of Congress and a state statute, the state law "must yield to the law of Congress."<sup>157</sup>

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148. *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935); *A.L.A. Schechter Poultry Corp. v. U.S.*, 293 U.S. 495 (1935).

149. STEPHEN G. BREYER ET AL., *ADMINISTRATIVE LAW AND REGULATORY POLICY* 44 (5<sup>th</sup> ed. 2002).

150. FOX, *supra* note 143, at 4-5.

151. *Id.* at 5.

152. 5 U.S.C. §§ 551-808 (2000).

153. FOX, *supra* note 143, 195-197.

154. *Id.* at 6.

155. *Id.*

156. *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824).

157. *Id.* at 31.

In *Napier v. Atlantic Coast Line*,<sup>158</sup> the Supreme Court took up the conflict between the Interstate Commerce Commission's rules and state law. The Court held that when Congress grants power to an agency to prescribe rules, Congress "intends to occupy the field" and state law must yield.<sup>159</sup>

In *Rice v. Santa Fe Elevator Corporation*,<sup>160</sup> the Court took up the issue over what happens when states have traditionally occupied the field and Congress subsequently legislates. The Court began "with the assumption that the historic police powers of the States were not to be superseded by the Federal Act, unless that was the clear and manifest purpose of Congress."<sup>161</sup> The Court emphasized that the scheme of federal regulation has to be "pervasive as to make reasonable the inference that Congress left no room for the States to supplement it."<sup>162</sup>

The current lack of an adequate regulatory framework to ensure the safety of prescriptions purchased online demonstrates the need for Congress to act and give the appropriate federal agencies broad power to fashion a solution for the current regulatory vacuum. If Congress acts and occupies the field, state laws that conflict with federal law will have to yield. This does not mean there is no role for the states, only that the federal government will take on the primary responsibility for regulating Internet prescription drug sales.

### B. Making the Case for Federal Regulation

Each federal body now regulates a small portion of online drug sales. The result is a lack of cohesiveness among the regulations. Proper federal regulation can only be achieved if the federal government devises a thorough legislative framework that outlines the policy goal. This all-encompassing legislation should allow the agencies to work closely together to share information on implementation of new laws and to share power when regulating online pharmacies.

This would not require the creation of a new federal agency. The federal government can actively and effectively regulate online pharmacies by giving one agency, such as the FDA, primary authority for regulating the sale of prescription drugs over the Internet. Even

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158. *Napier v. Atlantic Coast Line*, 272 U.S. 605 (1926).

159. *Id.* at 611.

160. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947).

161. *Id.* at 230.

162. *Id.*

though the FDA does not currently have explicit authority to regulate Internet prescription drug sales, Congress has the power to amend and broaden an agency's enabling act.<sup>163</sup>

Congress can act under this authority to safeguard consumers purchasing prescriptions over the Internet. The FDA should be given the necessary authority and resources to monitor the sale of prescription drugs online, regulate the importation of drugs from abroad, set up labeling standards for drugs that come from overseas, and ensure that all drugs that enter the country have been approved by the FDA for domestic use. In addition, the FDA should continue to have primary responsibility for enforcing all aspects of drug labeling.<sup>164</sup> Moreover, the DOJ could use its own sub-agencies, such as the DEA, to continue to enforce the Controlled Substances Act.<sup>165</sup> The FBI, for example, could investigate violations of the law that do not involve abuse of controlled substances.

Ideally, each agency's authority to promulgate rules would be clearly marked; however, that is not always the case. For instance, the FTC's current role in ensuring truthful labeling overlaps with the FDA's role in ensuring that prescription labels are what they purport to be. Any new legislative efforts from Congress should strive to delineate each agency's power and to eliminate any duplicative efforts.

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163. Recently, Congress amended the FTC's enabling act to allow it to "implement and enforce a national do-not-call registry." H.R. 3161, 107th Cong. (2003). Before, the FTC could not enforce a national do-not-call registry because it exceeded the FTC's authority under its enabling act. Under the Telephone Consumer Protection Act of 1991 (TCPA), 47 U.S.C. § 227 (c)(1)(A)-(E), (c)(3) (2004), the Federal Communications Commission (FCC) was given the authority to promulgate rules to protect consumers from receiving unwanted telemarketing calls. The TCPA did not require the FCC to implement a national do-not-call registry, and the FCC chose not to create the registry. *Mainstream Marketing Services, Inc. v. FTC*, 284 F. Supp. 2d 1151 (2003). The Telemarketing Act of 1994, 15 U.S.C. § 6102 (2004), gives the FTC power to promulgate rules to curb "abusive telemarketing practices." In *Mainstream Marketing Services*, however, Judge Nottingham found the FTC's rules did not allow it to create a federal registry. *Mainstream Marketing Services*, 284 F. Supp. 2d at 1151. The decision generated a public outcry leading Congress to amend the FTC's enabling act the next day. H.R. 3161, 108th Cong. (2003).

164. 15 U.S.C. § 1451 (2003).

165. 21 U.S.C. § 801 (2004).



### C. Current Legislative Efforts

The urgency of addressing the current regulatory vacuum grows exponentially as online drug sales continue to expand in the United States' health care landscape.<sup>166</sup> While lawmakers are aware of the need to address the current legislative vacuum,<sup>167</sup> various obstacles have thus far prevented such action. Lack of agreement amongst lawmakers on how to proceed,<sup>168</sup> the powerful lobby of drug companies,<sup>169</sup> and a lack of consumer education<sup>170</sup> are some of the more notable examples. Despite such obstacles, Congress now appears ready to legislate in this field. The Senate has identified Internet prescription drug sales and Internet pharmacies as a critical component of any meaningful reform of Medicare.<sup>171</sup> In fact, a portion of the proposed Medicare legislation introduced in 2002 was devoted solely to the issue of Internet pharmacies.<sup>172</sup> The narrow victory of the Medicare Prescription drug legislation in the House of Representatives reflects a deep divide in Congress over the issue of how to address prescription drug sales.<sup>173</sup> Hence, any bill regulating Internet prescription drug sales will face an uphill battle before it can make its way to the President's desk.

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166. In 1999, Rep. Ron Klink (D-PA) voiced concern that "a Wild West world is unfolding before us, where many consumers are accessing potentially dangerous drugs with little or no practical guidance. Yet because it is e-commerce, there is a mentality: It must be progress." Flaherty & Gaul, *supra* note 11, at A1.

167. *Id.*

168. Scott, *supra* note 43, at 412.

169. In 2002 the Pharmaceutical Research and Manufacturers of America donated \$143,000 to Democrats and over \$3 million to Republicans. Other pharmaceutical donors included Aventis (\$542,000 to Republicans), DuPont Pharmaceuticals (\$5,000 to Democrats). See COMMON CAUSE, THE SOFT MONEY LAUNDROMAT, at <http://www.commoncause.org/laundromat/stat/topdonors01.htm> (last visited May 13, 2004).

170. Health Care Expansion and Quality Improvement Act of 2003, S. 10, 108th Cong. (2003).

171. *Id.*

172. S. 10 § 503B.

173. *Id.* The House approved the measure with 221 yeas and 208 nays.

### 1. *The Prescription Drug Affordability Act*

The Prescription Drug Affordability Act (PDAA)<sup>174</sup> was introduced in the House of Representatives in 2003.<sup>175</sup> The PDAA would amend the Federal Food, Drug and Cosmetic Act (FDCA) to require that accurate information be posted on the website of an Internet pharmacy selling online.<sup>176</sup> The goal of this proposed legislation would be to reduce barriers of importation for FDA approved drugs. Anyone who wants to import a drug would have to submit an application to the FDA, which then would approve the drug importation unless the drug is adulterated or not approved for use in the U.S.

The PDAA would forbid the federal government from regulating any Internet sales of FDA approved drugs if the drug importation were done by a state-licensed pharmacist.<sup>177</sup> The PDAA's sponsor<sup>178</sup> believes that the federal government should have a laissez-faire approach to Internet prescription drug sales and that "letting the free market work is the best means of lowering the cost of prescriptions drugs."<sup>179</sup> This bill would prevent the HHS Secretary from taking any action against Internet pharmacies if the sale is made in compliance with the Act.<sup>180</sup>

As of the time of this writing, the PDAA was still in the Subcommittee of Health without any major activity.<sup>181</sup> While the bill takes a step in the right direction by securing cheaper prescription drugs through lawful importation, the bill falls short of the needed regulatory reform necessary to address consumer safety. In fact, it limits the role of federal agencies in protecting consumers, perpetuating the current problems associated with imposing on states the burden to regulate online pharmacies.

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174. See Prescription Drug Affordability Act, H.R. 616, 108th Cong. (2003).

175. *Id.* (introduced in the House of Rep. on Feb. 5, 2003).

176. H.R. 616 § 202.

177. *Id.*

178. Rep. Ron Paul, R-TX (107th Cong., 2003).

179. 149 CONG. REC. E190 (daily ed. Feb. 12, 2003) (statement of Rep. Ron Paul), available at <http://thomas.loc.gov/cgi-bin/query/D?r108:1:/temp/r1082OYC37::> (last visited May 13, 2004).

180. H.R. 616 § 202.

181. *Id.* H.R. 616 was introduced on Feb. 5, 2003, and on Feb. 12, 2003, it was referred to the Subcommittee on Health. At the time of publication, there has been no further action on this bill.

## 2. *Additional Legislative Proposals*

Recently, two other legislative proposals dealing with online sales of prescription drugs were introduced. The first one, the Internet Pharmacy Consumer Protection Act,<sup>182</sup> amends the FDCA by prohibiting a person from dispensing a prescription drug if the purchaser submitted the purchase order from an Internet site that does not provide the following required information: name, address of the principal place of business, and telephone number of the dispenser; disclosure of each state in which the person is authorized by law to dispense prescription drugs; and name of each individual who serves as a pharmacist for the site and each state that she is authorized to dispense prescription drugs.<sup>183</sup> In addition, if the site provides medical consultation, then additional requirements must be met, such as disclosure of the name of each individual who provides such consultations and each state in which she is licensed or authorized by law to provide such services.<sup>184</sup> The proposed legislation would prohibit Internet prescription sales without an "appropriate medical relationship."<sup>185</sup> The Act requires at least one in-person medical evaluation by a practitioner and a valid prescription.<sup>186</sup>

The Act would explicitly allow states to bring civil action in a United States District Court on behalf of its residents for violations.<sup>187</sup> Remedies available to the states include injunctive relief, damages, restitution, and attorney's fees.<sup>188</sup> The Act also provides for a two-year, \$100,000 per year grant to the FSMB for the purposes of (1) identifying Internet sites that are in violation of state or federal laws; (2) investigating violations; and (3) submitting evidence to the state pharmacy licensing boards, the Attorney General, and the HHS Secretary for further investigation.<sup>189</sup>

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182. Internet Pharmacy Consumer Protection Act, H.R. 3880, 108th Cong. (2004).

183. H.R. 3880 § 2 (a).

184. *Id.*

185. *Id.* § 2(b).

186. *Id.*

187. *Id.* § 2(c).

188. *Id.*

189. *Id.* § 3(c).

As of this writing, the Internet Pharmacy Consumer Protection Act<sup>190</sup> is in the Subcommittee on Health. It is still too early for any further action to be contemplated. If passed, this bill would strike the correct balance between the federal government and state governments because it gives the FDA power to regulate, and the Attorney General and the states power to prosecute. It protects consumers by requiring substantial disclosure from online pharmacies, and it ensures physicians rendering medical advice are licensed and have a medical relationship with the patient by having a minimum of one in-person consultation.<sup>191</sup> The Act looks to the federal government to secure broad consumer protection and gives federal agencies the power to enforce it while at the same time preserving an enforcement role for states; the agency can obtain injunctive relief and effectively shut down the fraudulent online pharmacy without needing each state to bring an action.<sup>192</sup> This measure allows states to work together with each other and with the federal government to strike the correct balance that will afford consumers the greatest protection without eliminating the states' traditional role in pharmacy licensing and regulation.

### *3. Prescription Drug Abuse Elimination Act of 2004*

The second most recent legislative proposal is the Prescription Drug Abuse Elimination Act of 2004.<sup>193</sup> The Act provides states with grants for establishing a controlled substance prescription drug monitoring program database. This database contains the name and address of the user, the quantity dispensed, the number of refills ordered, the estimated number of days for which such quantity should last, whether it was a first-time request or a refill, date of dispensing, and the date of the original prescription.<sup>194</sup> States are required to make the database available to law enforcement and bona fide treating physicians.<sup>195</sup>

This measure aims at controlling prescription drug abuse on the Internet. While the goal of the legislation is commendable, it raises privacy questions and places a heavy administrative burden on States

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190. H.R. 3880 was introduced on March 3, 2004.

191. H.R. 3880 §503B (b)(2)(A).

192. *Id.* §503B (c)(1).

193. Prescription Drug Abuse Elimination Act of 2004, H.R. 3870, 108<sup>th</sup> Cong. (2004).

194. *Id.*

195. *Id.*

to gather and maintain a database with such detailed information. This legislation helps prevent drug abuse by those who seek to use the Internet for such purposes. However, it does not address the need for protection for the innocent consumers who seek to legally purchase safe medications online.

#### *D. Outlining a Workable and Beneficial Federal Regulatory Role*

Circumstances under which a doctor may appropriately prescribe medications online<sup>196</sup> should be limited to those instances in which traditional doctors appropriately prescribe drugs relying solely on the patient's medical history, without the need for a face-to-face consultation. To safeguard this process, "online doctors" should be required to obtain a copy of the medical records on file with the patient's traditional doctor in order to determine potential adverse reactions and examine the patient's medical history. The traditional doctor may also have a role to play as a middleman. The patient would shop for drug prices online, and the doctor's office would then contact the online pharmacy to provide the prescription. Or, taking that one step further, states could set up an online exchange system where pharmacies compete on prices the same way as the online home mortgage database system (i.e., Lendingtree.com). The system could be used by patients who would use their regular prescriptions written at the doctor's office.

Medicine in the twenty-first century provides physicians with an array of choices for treating a malady. Decisions regarding which drugs to order, potential fatal drug interactions, and whether the drugs meet FDA's safety standards simply cannot be made by the consumer in a regulatory vacuum. The consumer lacks both knowledge and the necessary information to make those decisions and will be exploited in the absence of a coherent regulatory regime.

Legalizing online pharmacies through a uniform regulatory framework like that above also opens them to greater monitoring and scrutiny by the managed care corporations.<sup>197</sup> Eliminating the "secrecy" in which many online pharmacies operate will help distinguish those that are legitimate from those that are fraudulent.

Without such a uniform federal approach, given the discrepancies in state laws and lack of coordination among numerous federal agencies

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196. Scott, *supra* note 43, at 412.

197. Haney, *supra* note 62, at 581-582.

in the area of online prescriptions, some consumers will go virtually unprotected. The federal government has the “legal machinery” in place to develop uniform regulation and to enforce and prosecute violations through administrative agencies. State governments have a role to play, not only in assisting the federal government with enforcement matters, but also in regulating those areas left unregulated by the federal government. Through the states’ individual boards of pharmacy, states can set standards for pharmacists and physicians and issue licenses. They can also impose additional penalties and prevent pharmacies from doing business within the state.

The case for uniform federal regulation is founded on the notion that a consumer’s life should not be placed in jeopardy merely because his state has yet to begin the process of examining the risks associated with online prescribing and dispensing of medication. Even if state governments pass legislation in an attempt to regulate the field, a state acting in its individual capacity simply does not have the power or the financial resources to prosecute pharmacies located in other states or, more importantly, overseas.

In the circumstance of foreign pharmacies, there is an even stronger case for uniform federal regulation. Under the Constitution, states cannot levy import duties<sup>198</sup> in order to discourage drug importation due to safety issues. The executive branch is the only branch of government that can appoint Ambassadors and enter into treaties with other nations.<sup>199</sup> The channels of diplomacy can be used in an attempt to rein in illegal foreign pharmacies. States simply do not have the power to carry out diplomatic efforts on behalf of the United States. Likewise, states do not have the power to impose unilateral sanctions or trade embargos to compel nations where rogue pharmacies operate to comply with U.S. laws.

If allowed to operate freely and with proper regulation, online pharmacies will become powerful competitors in the pharmacy field. Their lower prices will provide a powerful incentive for traditional brick and mortar pharmacies to lower their own prices in order to remain competitive. Traditional pharmacies can then pressure drug manufacturers to decrease their robust profits and provide the American consumer with drugs that are equivalent in price to its Canadian and Mexican counterparts.

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198. U.S. Const. art. I, § 10 cl. 2.

199. U.S. Const, art. II, § 2 cl. 2.

## VII. CONCLUSION

Maintaining the status quo is simply untenable. The current drug regulation regime has grown obsolete in light of the burgeoning online prescription drug industry, and does not reflect the reality of e-commerce. The current patchwork of federal regulation puts consumer safety at risk. Congress must act with the people's interest in mind and provide for uniform federal regulation of Internet prescription drug sales.